Risk Factors Comparison 2024-03-14 to 2023-03-15 Form: 10-K

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~~Investing in our securities involves a high degree of risk. You should carefully consider the risk factors discussed below as well as other information we include in this Annual Report, including our consolidated financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the market price of our securities could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward- looking statements as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. For a summary of the risk factors included in this Item 1A and for further details on our forward- looking statements, see " Cautionary Note Regarding Forward- Looking Statements and Summary of Risk Factors " on page 1.~~ Risks Related to Our Financial Position and Capital Requirements ● We have a limited operating history that you can use to evaluate us, and the likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company. ● ~~Our wholly owned subsidiary, Quoin Inc., commenced operations in 2018. As such, we have a limited operating history and our operations are subject to all of the risks inherent in the establishment of a new business enterprise, including a lack of operating history. Since inception, our operations have been primarily limited to acquiring and licensing intellectual property rights, undertaking research and conducting preclinical and clinical studies for our initial programs and negotiating and executing the Merger and financings. We have not yet obtained regulatory approval for any product candidates. Consequently, any predictions about our future success or viability, or any evaluation of our business and prospects, may not be accurate. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company starting a new business enterprise and the highly competitive environment in which we will operate. Since we have a limited operating history, we cannot assure you that our business will be profitable or that we will ever generate sufficient revenues to meet our expenses and support our anticipated activities. In addition, there is no guarantee that any of our product candidates with ever receive approval from the U. S. Food and Drug Administration, or the " FDA. " We cannot be certain that our business strategy will be successful or that we will be solvent at any particular time. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with the early stages of the development of any company. If we fail to address any of these risks or difficulties adequately, our business will likely suffer. Because of the numerous risks and uncertainties associated with developing and commercializing our products, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of products in the medical and pharmaceutical industries. We may never successfully commercialize our products and our business may fail.~~ We have incurred significant losses since our inception and have limited cash available for our operations. ~~To date, we have not commercialized any products and have not generated any revenue. We have devoted most of our financial resources to research and development, including our preclinical and ongoing clinical development activities. To date, we have funded our operations primarily through our founders' funding expenditures and the sale of equity and convertible securities. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we: ● have initiated clinical development of our product candidates, including our first lead product — QRX003 — a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare ® technology, to treat Netherton Syndrome (" NS "); ● further enhance our internal control systems; ● initiate the development of additional product candidates for other rare disease indications; ● acquire or in- license other products and technologies and advance those product candidates into clinical trials; ● seek marketing approvals for our product candidates that successfully complete clinical trials; ● ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; ● maintain, expand and protect our intellectual property portfolio; ● hire additional clinical, regulatory, research, executive and administrative personnel; and ● create additional infrastructure to support our operations and our product development and planned future commercialization efforts.~~ We have never generated any revenue from product sales or any other sources since inception, and may never be profitable. ~~Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic alliance partners, to successfully complete the development of, obtain the necessary regulatory approvals for and~~

commercialize our product candidates. We do not anticipate generating revenues from sales of our products until regulatory approval has been obtained, if ever. Our ability to generate future revenues from product sales depends heavily on our success in: ● completing our research and preclinical development of product candidates; ● initiating and completing clinical trials for product candidates with favorable results; ● seeking, obtaining, and maintaining marketing approvals for product candidates that successfully complete clinical trials; ● establishing and maintaining supply and manufacturing relationships with third parties; ● launching and commercializing product candidates for which we may obtain marketing approval, with an alliance partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure; ● maintaining, protecting and expanding our intellectual property portfolio; and ● attracting, hiring and retaining qualified personnel. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. In addition, our expenses could increase beyond expectations if we are required by the FDA or other foreign regulatory agencies to perform studies and trials in addition to those that we currently anticipate. 16Even if one or more of the product candidates that we independently develop is approved for commercial sale, we may incur significant costs associated with commercializing any approved product. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. We expect that we will need to raise additional capital, which may not be available on acceptable terms, or at all. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidates towards or through clinical trials. We may need to raise additional capital to support our operations and such funding may not be available to us on acceptable terms, or at all. We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. For example, our preclinical or clinical trials may encounter technical difficulties or be subject to delays or other issues. Any of these events may increase our development costs more than we expect. In order to support our long- term plans, we may need to raise additional capital or otherwise obtain funding through additional strategic alliances if we choose to initiate preclinical or clinical trials for new product candidates other than programs currently partnered. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, future product candidates. Any additional fundraising efforts may divert our management from our day- to- day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to: ● significantly delay, scale back or discontinue the development or commercialization of any future product candidates; ● seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or ● relinquish or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects. Changes in U. S. tax laws or regulations may increase tax uncertainty and adversely affect results of our operations and our effective tax rate. We may be subject to the Excise Tax (as defined below) included in the IRA in connection with redemptions of our ordinary shares or ADSs after December 31, 2022. In particular, an excise tax is imposed on " covered corporations " (generally, publicly- traded domestic corporations and publicly- traded foreign corporations treated as domestic corporations pursuant to Section 7874 of the Code) equal to 1 % of the fair market value of certain stock repurchased after December 31, 2022 (the " Excise Tax "). As a result of the consummation of the Merger, we should be treated as a domestic corporation and therefore as a covered corporation. Consequently, it is likely that the Excise Tax will generally apply to any redemptions of our ordinary shares or ADSs after December 31, 2022. The Excise Tax base is reduced by the fair market value of any issuances of the covered corporation' s stock during its taxable year. The fair market value of any of our ordinary shares or ADSs that are redeemed may exceed the fair market value of any of our stock issued during the same taxable year. Consequently, the Excise Tax may reduce the amount of cash we have available to shareholders. 17Risks -- **Risks** Related to the Discovery and Development of Product CandidatesPreclinical **Candidates ● Preclinical** and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from preclinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed. We have no products approved for commercial marketing and most of our product candidates are in preclinical development and clinical testing as is the case with our lead asset for NS, which is currently being tested in two separate clinical studies in NS patients. Moreover, the clinical development process can take several years, and there is no assurance that our clinical trials will be successful or that we will obtain marketing approvals for any of our product candidates from either the FDA or the EMA. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy of our product candidates. The success of our product candidates will depend on several factors, including the following: ● successfully implementing preclinical studies which may be predictive of clinical outcomes; ● successful enrollment in clinical trials and completion of those trials with favorable results; ● receipt of marketing approvals from applicable regulatory authorities; ● obtaining and maintaining patent and trade secret protection for current and future product candidates; ● establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and ● successfully commercializing our products, if approved, including successfully establishing a sales force, marketing and distribution infrastructure, whether alone or in collaboration with others. If we do not achieve one or more of these factors in a

timely manner or at all, we could experience significant delays or an inability to successfully complete the development or commercialization of our product candidates, which would materially harm our business. We may not be successful in our efforts to identify or develop potential product candidates. The success of our business depends primarily upon our ability to identify, develop and commercialize our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including: ● our research methodology may be unsuccessful in identifying potential product candidates; or ● potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unsuitable for administration in patients in clinical trials, unlikely to receive marketing approval or unmarketable. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. 18If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Before obtaining marketing approval from regulatory authorities for the sale of product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results or planned interim analyses of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Events which may result in a delay or unsuccessful completion of clinical development include: ● delays in reaching an agreement with the FDA or other regulatory authorities on final trial design, including selection of dose and clinical outcome assessments and related efficacy endpoints ● delays in obtaining from the FDA, or comparable foreign regulatory authority, authorization to administer an investigational new drug product to humans through the submission or acceptance of an IND or similar foreign application; ● imposition of a clinical hold of our clinical trial operations or trial sites by the FDA or other regulatory authorities; ● delays in reaching agreement on acceptable terms with prospective contract research organizations (" CROs ") and clinical trial sites; ● our inability to adhere to clinical trial requirements directly or with third parties such as CROs; ● clinical trial site or CRO non-compliance with good clinical practices (" GCPs "), good laboratory practices, or other regulatory requirements; ● inability or failure of clinical trial sites to adhere to the clinical trial protocol; ● delays in obtaining required IRB approval at each clinical trial site, or an IRB reversing such approval resulting in the suspension or termination of a trial at that; ● delays in recruiting and retaining suitable patients to participate in a trial particularly for a rare disease such as NS; ● delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites; ● delays in having patients complete participation in a trial or return for post- treatment follow- up; ● delays caused by patients dropping out of a trial due to protocol procedures or requirements, product side effects or disease progression; ● clinical sites dropping out of a trial to the detriment of enrollment; ● time required to add new clinical sites; or ● delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials. Accordingly, we cannot be sure that we will submit INDs on the expected timelines and we cannot be certain the FDA or foreign regulatory agencies such as the EMA, will allow us to progress into clinical trials based on the submission of any IND. 19If we are required to conduct additional clinical trials or other testing of any product candidates beyond those that are currently contemplated, are unable to successfully complete clinical trials of any such product candidates or other testing, or if the results of these trials or tests are not positive, are only modestly positive or if there are safety concerns, we may: ● be delayed in obtaining marketing approval for our future product candidates; ● not obtain marketing approval at all; ● obtain approval for indications or patient populations that are not as broad as originally intended or desired; ● obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; ● be subject to additional post-marketing testing requirements; or ● have the product removed from the market after obtaining marketing approval. Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales. Any of our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. While we have not yet initiated clinical trials for any of our product candidates, it is possible that there will be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment, the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. Further, clinical trials by their nature test product candidates in only small

samples of the potential patient populations. With a limited number of patients and limited duration of exposure in such trials, rare and potentially severe side effects of our product candidates may not be uncovered until a significantly larger number of patients are exposed to the product candidate. If any of our product candidates receive marketing approval, and causes serious, unexpected, or undesired side effects, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw, suspend, or limit their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy; ● regulatory authorities may require the addition of labeling statements, such as black box warnings or contraindications; ● we may be required to change the way the product is administered or conduct additional clinical trials or post- marketing surveillance; ● we could be sued and held liable for harm caused to patients; or ● our reputation may suffer. 20Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our future products and impair our ability to generate revenues from the commercialization of these products. Even if we complete the necessary preclinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a future product. We cannot commercialize a product until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for many reasons including: ● regulatory authorities disagreeing with the design or implementation of our clinical trials; ● such authorities may disagree with our interpretation of data from preclinical studies or clinical trials; ● such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States; ● unfavorable or unclear results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval; ● serious and unexpected drug- related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; ● the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a New Drug Application (" NDA ") or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials; ● such authorities may disagree regarding the formulation, labeling and / or the specifications of our product candidates; ● such authorities may find deficiencies in the manufacturing processes, testing systems or facilities of our third- party manufacturers with which we contract for clinical and commercial supplies; or ● regulations of such authorities may significantly change in a manner rendering our clinical data insufficient for approval. Additional delays may result if an FDA advisory committee recommends restrictions on approval or recommends non-approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory challenges. Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. The FDA may also require risk evaluation and mitigation strategies as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Additionally, the manufacturing processes, packaging, distribution, adverse event reporting, labeling, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing FDA regulatory requirements, in addition to other potentially applicable federal and state laws. These 21requirements include monitoring and reporting of adverse events (" AEs ") and other post- marketing information and reports, registration, as well as continued compliance with current good manufacturing practice (" cGMP ") regulations. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. If we or a regulatory agency discovers previously unknown problems with a product such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may: ● issue a warning or untitled letter asserting that we are in violation of the law; ● seek an injunction or impose civil or criminal penalties or monetary fines; ● suspend or withdraw regulatory approval; ● suspend any ongoing clinical trials; ● refuse to approve a pending NDA or supplements to an NDA submitted by us; ● seize product or require a product recall; or ● refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our future products, if approved, and generate revenues. We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates. ● Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States, or if the disease or condition affects more than 200, 000 individuals in the United States and there is no reasonable expectation that the cost of developing the drug for the type of disease or condition will be recovered from sales of the product in the United States. Orphan drug designation entitles a party to financial incentives, such as tax advantages and user

fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in certain circumstances, such as a showing of clinical superiority (i. e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. We intend to apply for orphan drug designation in the United States for QRX003 for the treatment of NS. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. Even if we obtain orphan drug designation for a product candidate in specific indications, we may not be the first to obtain regulatory approval of the product candidate for the orphan- designated indication. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for orphan designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other future 22product candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. We may pursue Rare Pediatric Disease designation for QRX003 for the treatment of NS or other of our product candidates. There is no assurance that we will obtain such designation. Moreover, a Rare Pediatric Disease designation by the FDA does not guarantee that the NDA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that any of our product candidates will receive marketing approval. ● Under the Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying NDA for the treatment of a rare pediatric disease, the sponsor of such an application may be awarded a transferable rare pediatric disease priority review voucher that can be used to obtain priority review for a subsequent NDA or BLA. We intend to pursue Rare Pediatric Disease designation for QRX003 for the treatment of NS, but there is no assurance that we will receive such designation. On December 27, 2020, the Creating Hope Reauthorization Act extended the Rare Pediatric Disease Priority Review Voucher Program, and after September 30, 2024, the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. However, there is no guarantee that any of our product candidates will be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that an NDA will meet the other eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease designation does not lead to faster development or regulatory review of the product, or increase the likelihood that it will receive marketing approval. We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success. As a result of our limited financial and human resources, we will have to make strategic decisions as to which product candidates to pursue and may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval. If successfully developed and approved, our product candidates may face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical and human resources than us, and may be better equipped to develop, manufacture, market and distribute products. Many of these companies operate large, well- funded research, development and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late- stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us. Currently, there are no approved products to treat NS. However, to our knowledge, there are a number of therapeutic products at various stages of development for the treatment of NS, including candidates from LifeMax Laboratories, Inc., Krystal Biotech, Inc., Sixera Pharmaceuticals, ResVita Bio, and Azitra Inc. Currently, to the best of our knowledge, there are no active studies on NS patients being conducted under an open IND by any of these companies. We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research 23institutions. Our competitors may have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and

acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, drug products that are more effective or less costly than any product candidate that we may develop. All of our programs are in either preclinical or clinical development and targeted toward indications for which there may be other product candidates in clinical development. We may face competition from other drugs currently approved or that may be approved in the future for the same therapeutic indications as our product candidates. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug development to: ● develop therapeutics that are superior to other products in the market; ● attract qualified scientific, product development and commercial personnel; ● obtain patent and / or other proprietary protection for our product candidates; ● obtain required regulatory approvals; and ● successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapeutics. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. We will not achieve our business plan if the acceptance of any of these products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or choose to reserve our future products for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing product candidates before we do, which would have a material adverse impact on our business. The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors. The degree of market acceptance of any product candidates will depend on a number of factors, including: ● demonstration of clinical safety and efficacy compared to other products; ● the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors; ● the prevalence and severity of any AEs; ● limitations or warnings contained in the FDA- approved label for such products; ● availability of alternative treatments; ● pricing and cost- effectiveness; ● the effectiveness of our, or any of our collaborators', sales and marketing strategies; 24 ● our ability to obtain hospital or payor formulary approval; ● our ability to obtain and maintain sufficient third- party coverage and adequate reimbursement; and ● the willingness of patients to pay out- of- pocket in the absence of third- party coverage. If a product is approved but does not achieve an adequate level of acceptance by physicians, patients and healthcare payors, we may not generate sufficient revenues from such product and we may not become or remain profitable. Such increased competition may decrease any future potential revenue for future product candidates due to increasing pressure for lower pricing and higher discounts in the commercialization of our product. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues. We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market any products that may be approved, we must build our sales, marketing, managerial and other non- technical capabilities or make arrangements with third parties to perform these services. With respect to future programs, we may rely completely on an alliance partner for sales and marketing. In addition, we may enter into strategic alliances with third parties to commercialize other product candidates, if approved, including in markets outside of the United States and Europe or for other large markets that are beyond our resources. Although we intend to establish a sales organization if we are able to obtain approval to market any product candidates in the United States, and Europe we will also consider the option to enter into strategic alliances for future product candidates in the United States and Europe if commercialization requirements exceed our available resources. This will reduce the revenue generated from the sales of these products. Any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates, if approved, or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates, if approved, to healthcare professionals and in geographical regions, including the United States and Europe, that will not be covered by our own marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates that may be approved, our ability to generate revenues from product sales will be adversely affected. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. If we obtain approval to commercialize any approved products outside of the United States and Europe, a variety of risks associated with international operations could materially adversely affect our business. If we obtain approval to commercialize any approved products outside of the United States and Europe, we expect that we will be subject to additional risks related to entering into international business relationships, including: ● different regulatory requirements for drug approvals in foreign countries; ● differing payor reimbursement regimes, governmental payors or patient self- pay systems and price controls; ● reduced protection for intellectual property rights; ● unexpected changes in tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; 25 ● foreign taxes, including withholding of payroll taxes; ● foreign currency fluctuations, which could result

in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. Coverage and adequate reimbursement may not be available for our product candidates, if approved, which could make it difficult for us to sell products profitably. Market acceptance and sales of any product candidates that we develop will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third- party payors, such as private health insurers, government payors and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that coverage and adequate reimbursement will be available for any future product candidates. In the United States, the Centers for Medicare & Medicaid Services (" CMS "), an agency within the U. S. Department of Health and Human Services, decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates. Inadequate reimbursement amounts may reduce the demand for, or the price of, our future products. Further, one payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize product candidates that we develop and that may be approved. Thus, even if we succeed in bringing a product to market, it may not be considered medically necessary or cost- effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell products profitably. These legislative and / or regulatory changes may negatively impact the reimbursement for drug products, following approval. The availability of numerous generic treatments may also substantially reduce the likelihood of reimbursement for our future products. We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. For instance, government and private payors who reimburse patients or healthcare providers are increasingly seeking greater upfront discounts, additional rebates and other concessions to reduce prices for pharmaceutical products. If we fail to successfully secure and maintain reimbursement coverage for our future products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our future products and our business will be harmed. In addition, in some non- U. S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U. S. and generally tend to be priced significantly lower. 26Risks -- **Risks** Related to Our Reliance on Third Parties**We** -- **Parties ● We** rely on third parties to conduct some aspects of our compound formulation, research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such formulation, research or testing. ● We do not expect to independently conduct all aspects of our drug development activities, compound formulation research or preclinical studies of product candidates. We currently rely **, or will** and expect to continue to rely on third parties to conduct some or all aspects of our preclinical studies and formulation development. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements , it could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the necessary preclinical studies to enable us to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates. We rely on third- party manufacturers to produce the supply of our preclinical product, clinical product candidates and commercial supplies of any approved product candidates. Reliance on third- party manufacturers entails risks, including risks that we would not be subject to if we manufactured the product candidates ourselves. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our third- party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third- party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our third- party manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day- to- day control over the operations of our third- party

manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs. Other risks of reliance on third- party manufacturers include: ● the inability to meet any product specifications and quality requirements consistently; ● a delay or inability to procure or expand sufficient manufacturing capacity; ● manufacturing and product quality issues related to scale- up of manufacturing; ● costs and validation of new equipment and facilities required for scale- up; ● the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms; ● termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; 27 ● the reliance on a limited number of sources, and in some cases, single sources for raw materials, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell future product candidates in a timely fashion, in sufficient quantities or under acceptable terms; ● the lack of qualified backup suppliers for any raw materials that are currently purchased from a single source supplier; ● operations of our third- party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; ● carrier disruptions or increased costs that are beyond our control; and ● the failure to deliver products under specified storage conditions and in a timely manner. Any of these events could lead to clinical study delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products, if approved. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production. We rely on limited sources of supply for the drug substance of product candidates and any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates. We currently have established manufacturing relationships with one API supplier and one drug product supplier and we are evaluating several other potential suppliers who manufacture raw materials and the drug substance used to create our product candidates. The availability of such suppliers to manufacture raw materials and drug substance for our product candidates in sufficient quantities for evaluation in preclinical or clinical studies or, if our product candidates are approved, for commercial supply may be limited. Further, each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and its processes are required to be qualified by the FDA prior to commercialization. If supply from any vendor approved in the NDA is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredients on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue. Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization. Manufacturing of product candidates and conducting required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order to proceed with any clinical trials and obtain regulatory approval for commercial marketing. We may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical programs and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for product candidates or any approved products. We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs will not relieve us of our regulatory responsibilities. 28We and our CROs will be required to comply with the FDA' s or other regulatory agency' s GCPs, for conducting, recording and reporting the results of IND- enabling studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA and non- U. S. regulatory agencies enforce these GCPs through periodic inspections of trial sponsors, CROs, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or applicable non- U. S. regulatory agency may require us to perform additional clinical trials before approving any marketing applications for the relevant jurisdiction. Upon inspection, the FDA or applicable non- U. S. regulatory agency may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a potential drug product. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process. Our CROs will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for such products and any product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed. We intend to rely on other third parties to package, store and

deliver drug products to the clinical trial sites for any clinical trials that we may conduct. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue. Risks Related to Our Intellectual PropertyIf -- **Property ● If** we are unable to obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets. ● Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in- licenses of intellectual property rights of others, for our product candidates, methods used to develop and manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. Our patent applications may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all of the potentially relevant prior art relating to patents and patent applications that we use in our business has been found; such prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold or patents we have in- licensed with respect to our programs or product candidates fail to issue or if their breadth or strength of protection is threatened, as applicable, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. A patent may be challenged through one or more of several administrative proceedings including post- grant challenges, re- examination or opposition before the USPTO or foreign patent offices. Any successful challenge of patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. 29Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, in certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding, known as an interference, can be initiated to determine which applicant is entitled to the patent on that subject matter. Such an interference proceeding provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to require us to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license at all, or on commercially reasonable terms. Our defense of a patent or patent application in such a proceeding may not be successful and, even if successful, may result in substantial costs and distract our management and other employees. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available however the life of a patent, and the protection it affords is limited. Once the patent life has expired for a product, we may be open to competition from generic medications. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, including processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. Although each of our employees agrees to assign their inventions to us through an employee inventions agreement, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information or technology are required to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA' s disclosure policies may change in the future, if at all. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non- patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Third- party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. 30Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications

with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management or employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. If we fail to obtain licenses or comply with our obligations in these agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are a party to intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various obligations on us. We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Our defense in a lawsuit may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares. 31We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.Other Risks Related to Our Business Operations and IndustryOur --- **Industry ● Our** future success depends on our ability to attract and retain key executives and to attract, retain and motivate qualified personnel. ● We are highly dependent on principal members of our executive team, and any reduction or loss of their services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies and clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit any executive or key employee or the loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.We may need to expand our organization and may experience difficulties in managing our growth, which could disrupt our operations. In the future we may expand our employee base to increase our managerial, scientific, operational, commercial, financial and other resources and we may hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and

integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure or give rise to operational mistakes, loss of business opportunities, loss of employees or reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. Moreover, if our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional or nonintentional failures to comply with the regulations of the FDA and non- U. S. regulators, to provide accurate information to the FDA and non- U. S. regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits 32stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, additional reporting requirements and / or oversight, particularly if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance, disgorgement, imprisonment, and contractual damages. Even if we are ultimately successful in defending against any such action, we could be required to divert financial and managerial resources in doing so and adverse publicity could result, all of which could harm our business. Future relationships with customers and third- party payors as well as certain of our business operations may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, further subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and by the U. S. states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include: ● The federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. Remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. A conviction for violation of the Anti- Kickback Statute requires mandatory exclusion from participation in federal healthcare programs. This statute has been applied to arrangements between pharmaceutical manufacturers and those in a position to purchase products or refer others, including prescribers, patients, purchasers and formulary managers. In addition, the Affordable Care Act amended the Social Security Act to provide that the U. S. government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act penalties for which are described below. ● Federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act (" FCA "), which imposes criminal or civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the federal government, including Medicare or Medicaid, that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false claim or statement. ● The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. ● The federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which imposes civil and criminal penalties for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), knowingly and willfully embezzling

or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare. 33 ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH "), and its implementing regulations, which imposes certain requirements on certain types of individuals and entities, such as healthcare providers, health plans and healthcare clearing houses, known as " covered entities, " as well as their " business associates, " independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, relating to the privacy, security and transmission of individually identifiable health information. ● The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians, physician assistants, certain types of advance practice nurses and teaching hospitals, and further requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties; and ● Many state and foreign law equivalents of each of the above federal laws, such as: anti- kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In addition, the European Union (" EU ") has established its own data security and privacy legal framework, including but not limited to Directive 95 / 46 / EC (the " Data Protection Directive "). The European General Data Protection Regulation (" GDPR ") contains new provisions specifically directed at the processing of health information, higher sanctions and extra- territoriality measures intended to bring non- EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including regulation due to the GDPR. If our operations are found to be in violation of any of the laws described above or any other governmental regulations or laws that apply to us, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, additional reporting requirements and / or oversight, particularly if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Recent and future healthcare legislation may further impact our business operations. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the " ACA ") was enacted, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA included a number of provisions that may reduce the profitability of drug products, including revising the rebate methodology for covered outpatient drugs under the Medicaid Drug Rebate Program, extending Medicaid rebates to individuals enrolled in Medicaid managed care plans, and requiring drug manufacturers to pay an annual fee based on their market share of prior year total sales of branded programs to certain federal health care programs. 34Since its passage, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts to repeal or replace certain aspects of the ACA. Former President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. On December 22, 2017, former President Trump signed into law H. R. 1, " An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018, " informally titled the Tax Cuts and Jobs Act, which significantly revises the U. S. Internal Revenue Code of 1986, as amended (the " Code "). The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " Additionally, on December 23, 2019, former President Trump signed a spending bill that repealed the implementation of certain ACA- mandated fees, including the so- called " Cadillac " tax on certain high cost employer- sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non- exempt medical devices. On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by

Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the ACA and our business. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2 % per fiscal year, which started in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID- 19 pandemic, unless additional Congressional action is taken. The Medicare reductions were phased back in starting with a 1 % reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2 % reduction. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, also reduced Medicare payments to several categories of healthcare providers. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Recently, healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act (the " IRA "), in August 2022, which will, among other things, allow U. S. Department of Health and Human Services (" HHS ") to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high- expenditure single- source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. The IRA also made changes to Medicare Part D, which provides prescription drug benefits for seniors and people with disabilities. Medicare Part D enrollees once had a gap in their coverage (between the initial coverage limit and the point at which catastrophic coverage begins) where Medicare did not cover their prescription drug costs, known as the coverage gap. However, beginning in 2019, Medicare Part D enrollees paid 25 % of brand drug costs after they reached the initial coverage limit- the same percentage they were responsible for before they reached that limit- thereby closing the coverage gap from the enrollee' s point of view. Most of the cost of closing the coverage gap is being borne by innovator companies and the government through subsidies. Each manufacturer of an approved drug or biologic is required to enter into a Medicare Part D coverage gap discount agreement and provide a 70 % discount on those drugs dispensed to Medicare Part D enrollees in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D. Beginning in 2025, the IRA eliminates the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out- of- pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10 % of Part D 35enrollees' prescription costs for brand drugs below the out- of- pocket maximum, and 20 % once the out- of- pocket maximum has been reached. Although these discounts represent a lower percentage of enrollees' costs than the current discounts required below the out- of- pocket maximum (that is, in the coverage gap phase of Part D coverage), the new manufacturer contribution required above the out- of- pocket maximum could be considerable for very high- cost patients and the total contributions by manufacturers to a Part D enrollee' s drug expenses may exceed those currently provided. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, unanticipated adverse effects could result from the use of our future products or product candidates which may result in a potential product liability claim. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● impairment of our business reputation; ● withdrawal of clinical trial participants; ● costs due to related litigation; ● distraction of management' s attention from our primary business; ● substantial monetary awards to patients or other claimants; ● the inability to commercialize our product candidates; and ● decreased demand for our product candidates, if approved for commercial sale. We plan to obtain product liability insurance relating to the use of our therapeutics in clinical trials. However, such insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to obtain

or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in damage to our reputation and / or subject us to costs, fines or lawsuits. Our business and operations would suffer in the event of computer system failures, cyber- attacks or a deficiency in our cyber- security. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, 36are vulnerable to damage from computer viruses, malware, supply chain attacks, ransomware attacks, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions over the Internet, attachments to emails, persons inside our organization or inside external organizations on which we rely for support, systems, or hardware. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of business. Maintaining safeguards to comply with evolving security laws and to protect our systems and data may increase our operating costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and a delay in development of our drug candidates. We have been, and may in the future be, adversely affected by health epidemics and pandemics, including COVID- 19, which may significantly harm our business, prospects, financial condition and operating results. We face various risks related to public health issues, including epidemics, pandemics and other outbreaks, including the recent COVID- 19 pandemic. If the spread of COVID- 19 continues, the development of clinical supply materials could be delayed and enrollment of patients in our pending clinical trials may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials would have to shift resources to cope with the COVID- 19 pandemic and may limit access or close clinical facilities due to the COVID- 19 pandemic. Additionally, if trial participants are unable to travel to clinical study sites as a result of quarantines or other restrictions resulting from the COVID- 19 pandemic, we may experience higher drop-out rates or delays in clinical studies once commenced. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, stay- at- home or shelter- in-place orders, and business shutdowns. These measures are reintroduced, they may adversely impact our operations and the operations of our suppliers, vendors and business partners. The extent to which the COVID- 19 pandemic impacts our business, prospects and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration and spread of the pandemic, its severity, the actions to contain the virus or treat its impact and how quickly and to what extent normal economic and operating activities can resume. The COVID- 19 pandemic could materially disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell or securities, continue to slow down the overall economy or curtail consumer spending. Business interruptions could delay us in the process of developing our future products. We are vulnerable to natural disasters such as earthquakes and wild fires, as well as other events that could disrupt our operations. We do not carry insurance for earthquakes or other natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations. Risks Related to Us Being an Israeli **Company** ● CompanyShareholders ------- **Shareholders** may have difficulties enforcing a U. S. judgment, including judgments based upon the civil liability provisions of the U. S. federal securities laws, against us or our executive officers and directors, or asserting U. S. securities laws claims in Israel. ● Service of process upon us in Israel or upon our non- U. S. resident directors and officers may be difficult to obtain within the United States and it may be difficult to enforce judgments obtained in the United States against our non- U. S. directors and executive officers. In addition, we have been informed by our legal counsel in Israel that it may be difficult to assert claims under U. S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U. S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U. S. securities laws against us or our officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U. S. law is applicable to the claim. If U. S. law is found to be applicable, the content of applicable U. S. law must be proved as a fact, which can be a time- consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our officers and directors in Israel. 37Moreover, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel or due to, among other reasons, absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel. Your rights and responsibilities as our shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U. S. corporations. ● Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U. S.- based corporations. In particular, a shareholder of an Israeli company, such as us, has a

duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards us and other shareholders and to refrain from abusing its power in us, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to our articles of association, an increase of our authorized share capital, a merger, and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from taking advantage of other shareholders. In addition, a controlling shareholder (as defined below), or any shareholder who knows that it possesses the power to determine the outcome of a shareholders' vote, or who has the power to appoint or prevent the appointment of one of our office holders (as defined below), or who holds any other power in our regard, has a duty to act in fairness towards us. However, Israeli law does not define the substance of this duty of fairness. There is little Israeli case law addressing the provisions described above, and these provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U. S. corporations. Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders. Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders, and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies, and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the holder of a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95 % of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2 % of the company' s issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights). Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to those of our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax- free share exchanges to the same extent as U. S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances, but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred. Additional tax considerations or exemptions from the foregoing may apply to certain non- Israeli tax resident shareholders. These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders. 38Risks -- **Risks** Related to Ownership of Our ADSs and Ordinary SharesWe -- **Shares ● We** do not know whether a market for our securities will be sustained or what the trading price of our securities will be and as a result it may be difficult for you to sell our securities held by you. ● Although our ADSs trade on Nasdaq, an active trading market for the ADSs may not be sustained. It may be difficult for you to sell your ADSs without depressing the market price for the ADSs. As a result of these and other factors, you may not be able to sell your ADSs. Further, an inactive market may also impair our ability to raise capital by issuing securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using our equity as consideration. The requirements of being a publicly traded company may strain our resources and divert management' s attention. ● As a publicly traded company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act "), as well as rules subsequently implemented by the SEC and Nasdaq under such acts have imposed various requirements on public companies. Shareholder activism, the current political environment and the current high level of government regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes- Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs. ● Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes- Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Disclosing deficiencies or weaknesses in our internal controls, failing to remediate these deficiencies or weaknesses in a timely fashion or failing to achieve and maintain an effective internal control environment may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of the ADSs. If we cannot provide reliable financial reports

or prevent fraud, our operating results could be harmed. We may be unable to comply with the applicable continued listing requirements of Nasdaq. ● ADSs representing our ordinary shares are currently listed on Nasdaq. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a minimum closing bid price requirement for our ADSs of $ 1. 00 per ADS. There can be no assurance that we will be able to comply with the applicable listing standards. For example, if we were to fail to meet the minimum bid price requirement for 30 consecutive business days, we could become subject to delisting. Although Nasdaq may provide us with a compliance period in which to regain compliance with the minimum bid price requirement, we cannot assure you that we would be able to regain compliance within the period provided by Nasdaq. In order to regain compliance with such requirement, the closing bid price of our ADSs would need to meet or exceed $ 1. 00 per share for at least 10 consecutive business days during the compliance period. If we were not able to regain compliance within the allotted compliance period for this requirement or any other applicable listing standard, including any extensions that may be granted by Nasdaq, our ADSs would be subject to delisting. In the event that our ADSs are delisted from Nasdaq and are not eligible for quotation or listing on another market or exchange, trading of our ADSs could be conducted only in the over- the- counter market established for unlisted securities such as OTC Markets. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for our ADSs, which could cause the price of our ADSs to decline further. 39If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our traded securities, our securities price and trading volume could be negatively impacted. The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding the ADSs, or provide more favorable relative recommendations about our competitors, the price of the ADSs would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could negatively impact the price of the ADSs or their trading volume. The market price for our ADSs may be volatile. The market price for our ADSs is likely to be highly volatile and subject to wide fluctuations in response to numerous factors including the following: ● our failure to obtain the approvals necessary to commence clinical trials; ● results of clinical and preclinical studies; ● announcements of regulatory approval or the failure to obtain it, or changes or delays in the regulatory review process; ● announcements of new products or product enhancements by us or others; ● adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities; ● changes or developments in laws, regulations or decisions applicable to our product candidates or patents; ● any adverse changes to our relationship with manufacturers or suppliers; ● announcements concerning our competitors or healthcare industries in general; ● achievement of expected product sales and profitability or our failure to meet expectations; ● our commencement of or results of, or involvement in, litigation, including, but not limited to, any product liability actions or intellectual property infringement actions; ● any major changes in our board of directors, management or other key personnel; ● announcements by us of significant strategic partnerships, out- licensing, in- licensing, joint ventures, acquisitions or capital commitments; ● expiration or terminations of licenses, research contracts or other collaboration agreements; ● public concern as to the safety of our products that we, our licensors or others develop; ● success of research and development projects; ● developments concerning intellectual property rights or regulatory approvals; ● variations in our and our competitors' results of operations; 40 ● changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or the ADSs are covered by analysts; ● future issuances of ordinary shares, ADSs or other securities; ● general market conditions and other factors, including factors unrelated to our operating performance, such as natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency, including for example, the COVID- 19 pandemic), boycotts, adoption or expansion of government trade restrictions, and other business restrictions; and ● the other factors described in this " Risk Factors " section. These factors and any corresponding price fluctuations may materially and adversely affect the market price of the ADSs, which would result in substantial losses by our investors. In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of any particular company. These market fluctuations may also have a material adverse effect on the market price of the ADSs. We may be at risk of securities class action litigation. We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of our product candidates. In the past, medical, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with such events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs, divert management' s attention and resources, and have a material adverse effect on our business, operating results and prospects. Substantial future sales or perceived potential sales of our ordinary shares or ADSs in the public market could cause the price of our ADSs decline. Substantial sales of our ADSs on Nasdaq may cause the market price of our ADSs to decline. Sales by us or our security holders of substantial amounts of our ADSs or the perception that these sales may occur in the future, could cause a reduction in the market price of our shares ADSs. The issuance of any additional ordinary shares or any additional ADSs, or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our ADSs and will have a dilutive effect on our existing shareholders and holders of ADSs. Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote. We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. Pursuant to our equity incentive plan, our management may grant options to our employees, directors and consultants. We may sell ordinary shares

represented by ADSs, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, any of which may result in material dilution to our existing shareholders. New investors could also be issued securities with rights superior to those of our existing shareholders. We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities. ● We have not paid any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Moreover, the Companies Law imposes certain restrictions on our ability to declare and pay dividends. As a result, investors in our ADSs or ordinary shares will not be able to benefit from owning these securities unless their market price becomes greater than the price paid by such investors and they are able to sell such securities. We cannot assure you that you will ever be able to resell our securities at a price in excess of the price paid. 41If we pay dividends or other distributions, an ADS holder may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you. The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions, if any, in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In these cases, the depositary may determine not to distribute such property and hold it as " deposited securities " or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U. S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs. Provisions of our outstanding common warrants could discourage an acquisition of us by a third party. Certain provisions of our outstanding common warrants could make it more difficult or expensive for a third party to acquire us. The common warrants prohibit us from engaging in certain transactions constituting " fundamental transactions " unless, among other things, the surviving entity assumes our obligations under the common warrants. Further, the common warrants provide that, in the event of certain transactions constituting " fundamental transactions, " with some exceptions, holders of such warrants will have the right, at their option, to require us to purchase such common warrants from the holders for consideration of the same type as that offered to the holders of ordinary shares in such transaction in an amount determined pursuant to a formula set forth in such warrants. These and other provisions of our outstanding common warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you. Holders of ADSs must act through the depositary to exercise their rights. ● Holders of the ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law and our articles of association, the minimum notice period required to convene a shareholders meeting is not less than 35 or 14 calendar days, depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of the ADSs may not receive sufficient notice of a shareholders meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders meeting. You may be subject to limitations on transfer of your ADSs. **4** Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement. 42